

# **LAW AND REGULATIONS**

**Relating to**

**BOTTLED WATER**

**and**

**VENDED WATER**

**Excerpts from the  
CALIFORNIA HEALTH AND SAFETY CODE**

**the  
CALIFORNIA ADMINISTRATIVE CODE**

**the  
U.S. Pharmacopeia**

**and the  
CODE OF FEDERAL REGULATIONS**

**STATE OF CALIFORNIA  
DEPARTMENT OF HEALTH SERVICES  
FOOD AND DRUG BRANCH (MS-357)  
P.O. Box 942732  
601 N. 7th Street  
SACRAMENTO, CA 94234-7320**

*[Revised 9/14/99; A:\BW&VW\_LAW\_99.doc; MS Word]*

## CONTENTS

	PAGES
<u>Bottled, Vended, Hauled, and Processed Water</u> - California Health and Safety Code, Division 104, Part 5, Chapter 5, Article 12, Sections 111070 - 111195. Effective January 1, 1990.	3 - 15
<u>Sanitation Requirements for Vending Machines</u> - California Health and Safety Code, California Uniform Retail Food Facilities Law Sections 114200 - 114245	16
<u>Food Sanitation - Food Processing Establishments</u> - California Health And Safety Code Sections 111950 - 112055.	17 - 19
<u>Sanitation in Food Plants</u> - California Administrative Code, Title 17, Chapter 5, Subchapter 2, Group 1, Article 7, Sections 12245 - 12280.	20 - 21
<u>Bottled Water Quality Standards</u> - Title 21, Code of Federal Regulations, Section 165.110(b) [old Section 103.35].	22 - 34
<u>Processing and Bottling of Bottled Drinking Water</u> - Title 21, Code of Federal Regulations, Part 129.	35 - 40
<u>U. S. Pharmacopeia. Volume XXI</u> - Purified water monograph.	41
<u>Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food</u> - Title 21, Code of Federal Regulations, Part 110.	42 - 51

**BOTTLED, VENDED, HAULED, AND PROCESSED WATER**  
**CALIFORNIA HEALTH AND SAFETY CODE**  
**SECTIONS 111070 - 111195**

**111070.** (a) "Bottled water," means any water which is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. Bottled water shall not include water packaged with the approval of the department for use in a public emergency.

(b) "Vended water" means any water that is dispensed by a water-vending machine, retail water facility, or water from a private water source, or other water as defined in Section 111170 which is not placed by a bottler in sealed containers, and which is dispensed by a water-vending machine, retail water facility, water hauler, or any other person or facility for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Vended water," does not include water from a public water system which has not undergone additional treatment. Water sold without further treatment is not "vended water" and shall be labeled in accordance with paragraph (10) of subdivision (a) of Section 111170.

(c) "Water-bottling plant" means any facility in which bottled water is produced.

(d) A "water-vending machine" means any self-service device which, upon insertion of a coin, coins, or token, or upon receipt of payment by any other means, dispenses a unit volume of water to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

(e) "Water hauler," means any person who hauls water in bulk by any means of transportation if the water is to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

"In bulk," as used in this subdivision, means containers having capacities of 250 gallons or greater.

(f) "Retail water facility" means any commercial establishment where vended water is sold, and placed in customer's containers, or placed in containers sold or given to customers who come to the establishment to obtain water.

(g) "Private water source," means a privately owned source of water, other than a public water system, which is used for bottled or vended water and meets the requirements of an approved source for bottled water as defined in Section 129.3 of Title 21 of the Code of Federal Regulations.

(h) "Bottled water distributor" means any person, other than an employee or representative of a bottled water plant, who delivers bottled water directly to customers.

**111075.** (a) Any person who processes, packages, distributes, transfers, or stores bottled water or vended water shall comply with the good manufacturing practices described in Part 129 of Title 21 of the Code of Federal Regulations.

(b) Prior to bottling or vending water, the water shall be subjected to filtration and effective germicidal treatment by ozone, ultraviolet, carbon dioxide, or an equivalent disinfection process approved by the department, except that the requirements for filtration and germicidal treatment shall

not apply to mineral water as defined in and from a source that is subject to the council directive of the European Economic Community pertaining to natural mineral waters, dated July 15, 1980, or that is subject to any other natural mineral water standard in the country of origin which prohibits filtration and germicidal treatment, so long as both of the following conditions are met:

(1) The source and product are certified by the responsible authority in the country of origin as complying with microbiological standards at least equal to the standards of this article.

(2) The product complies with microbiological standards of this article.

(c) Bottled or vended water which originates from a surface water source which is not protected from surface contamination shall be subjected to ozonation, filtration, or another effective process which removes or destroys the cysts of the parasite *Giardia lamblia*. For the purposes of this section, a spring house, catchment basin, storage tank, or bore hole adjacent to a natural spring water source as defined in paragraphs (3) and (8) of subdivision (e) of Section 26594, is not a surface water source.

(d) Ollas or other water-holding dispensers, both refrigerated and nonrefrigerated, water-vending machines, and water dispensers in retail water facilities, shall be examined for cleanliness each time they are serviced by the distributor, bottler, retail water facility, or water-vending machine operator. When necessary, these dispensers shall be sanitized according to the methods described in Part 129 of Title 21 of the Code of Federal Regulations.

(e) Sanitary operations, equipment procedures, and process controls used in the treatment, storage, transport, or dispensing of water at a retail water facility shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) to (c), inclusive, of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.80.

(f) Sanitary operations, equipment, procedures, and process controls used in the treatment, storage, transfer, transport, or dispensing of water by water haulers, shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) and (b) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.89.

(g) The design and construction of wells, bore holes, catchment basins, spring houses, storage tanks, or other water-contact equipment used by private water sources shall comply with the requirements of the local regulatory authority. Sanitary operations, equipment procedures, and transfer controls used in the treatment, storage, transfer, or dispensing of water by private water source operators shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivision (a) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), (g), and (h) of Section 129.80.

(h) Bottled water may be processed through lines used also for other food products under the following conditions:

(1) Process lines, including storage tanks and associated equipment, shall be used exclusively for the production of bottled water, except for filling equipment, which may be used also for filling other food products.

(2) Before being used for the bottling of water, filling equipment which is designed to be cleaned in-place and which is used for filling other food products shall be thoroughly cleansed and

sanitized in-place in accordance with the manufacturer's specifications and in compliance with Section 129.80 of Title 21 of the Code of Federal Regulations and the supplementary procedures that follow in paragraphs (3) to (7), inclusive, of this section.

(3) Immediately following completion of filling operations for any other food product other than water, the filler shall be thoroughly rinsed internally and externally with potable water.

(4) In accordance with filler manufacturer's instructions, any parts which are not designed to be cleaned in-place shall be disassembled and removed. All of these parts shall be cleansed and sanitized prior to reassembly using appropriate cleansing and sanitizing procedures, as specified in subdivisions (c) and (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(5) All surfaces of the filler which do not contact food products shall be cleaned manually so as to render all surfaces clean and free of any residues.

(6) The filler shall be prepared and all appropriate connections made in accordance with the filler manufacturer's instructions to place the filler in the clean-in-place mode. The following procedures shall be followed:

(A) An alkaline cleaning solution of appropriate strength shall be recirculated through the filler to provide effective cleaning of all product contact surfaces, with a minimum recirculation time of 20 minutes at a temperature between 140 and 170 degrees fahrenheit.

(B) The cleaning solution shall be drained and followed with a potable water rinse-to-drain for the removal of all residual cleaner alkalinity. This step may be supplemented by the application of an acidified rinse prior to the potable water rinse in order to neutralize any residual alkalinity on product contact surfaces.

(7) Following reassembly of all parts to place the filler into the product mode and just prior to bottling water, the filler shall be sanitized in-place in accordance with procedures specified in subdivision (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(8) Any alternate cleaning, rinsing, or sanitizing operations or processes not described in this section shall be approved in writing by the department.

(i) Bottled water and bulk waters sold at retail shall not contact equipment, lines, tanks, or vehicles used for processing, packaging, holding, or hauling of any nonfood product.

**111080.** The quality standard requirements for bottled water and vended water, including mineral water, shall include all standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations, except that water labeled as mineral water shall exceed 500 milligrams per liter of total dissolved solids and may exceed the quality standards for chloride, copper, manganese, iron, sulfate, and zinc prescribed in Section 103.35 of Title 21 of the Code of Federal Regulations. The department may develop additional standards for chloride, copper, manganese, iron, sulfate, or zinc in mineral water that the department determines are reasonably necessary to protect the public health. In addition, bottled water and vended water, when bottled, shall comply with the following quality standards and any additional quality standards adopted by regulation which the department determines are reasonably necessary to protect the public health:

(a) Bottled water and vended water shall meet all maximum contaminant levels set for public drinking water that the department determines, after public comment, are necessary or appropriate so

that bottled water may present no adverse effect on public health. New or revised maximum contaminant levels or monitoring provisions adopted for bottled water by the United States Food and Drug Administration under the federal Food, Drug and Cosmetic Act that are more stringent than the state requirements for bottled water are incorporated into this chapter and are effective on the date established by the federal provisions unless otherwise established by regulations of the department.

(b) Bottled and vended water shall not exceed 10 parts per billion of total trihalomethanes or five parts per billion of lead unless the department establishes a lower level by regulation.

(c) Bottled and vended water shall contain no chemicals in concentrations which the United States Food and Drug Administration or the state department has determined may have an adverse effect on public health.

(d) Mineral water producers which bottle 5,000 gallons, or less, per week shall have until February 1, 1990, to comply with the quality standards for bottled water pursuant to this paragraph.

Mineral water producers may present to the state department data on consumption of mineral water and the health effects of inorganic elements which may be present as listed in the bottled water quality standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations.

**111085.** Polycarbonate resins manufactured after January 1, 1988, and intended for use in fabricating containers for water products defined in this article shall not contain in excess of three parts per million residual methylene chloride or in excess of 200 parts per million residual monochlorobenzene unless the department establishes a lower level by regulation. For the purpose of monitoring compliance with this section, the concentration of methylene chloride and monochlorobenzene shall not exceed one part per billion in water. "Polycarbonate resins" means the substances defined by Section 177.1580 of Title 21 of the Code of Federal Regulations except as modified by this section.

**111090.** Any owner or operator of a water-vending machine or other device from which any operator or customer dispenses vended water shall comply with the following standards of design, construction and sanitation and any additional standards adopted by regulation which the department determines are reasonably necessary to protect the public health. The water-vending machines or devices shall do all of the following:

(a) Comply with the construction and performance standards established by the department or by an independent authority approved by the department.

(b) Be designed and constructed to permit easy cleaning and maintenance of all exterior and interior surfaces.

(c) Have all parts and surfaces which come into contact with the water constructed of approved, corrosive-resistant and nonabsorbent material capable of withstanding repeated cleaning and sanitizing treatment.

(d) Have a recessed or guarded corrosion-resistant dispensing spout.

(e) Be designed so that all treatment of the vended water by distillation, ion exchange, filtration, ultraviolet light, reverse osmosis, mineral addition, or any other acceptable process is done in an effective manner.

- (f) Have an effective system of handling drip, spillage, and overflow of water.
- (g) Have a backflow prevention device approved by the department for all connections with the water supply.
- (h) Dispense water disinfected by ultraviolet light or other method approved by the department prior to delivery into the customer's container.
- (i) Be equipped with monitoring devices designed to shutdown operation of the machine when the disinfection unit fails to function, or shall be monitored daily at startup and manually shutdown whenever the unit fails to function.
- (j) Be equipped with a self-closing, tight-fitting door on the vending compartment, or enclosing the vending spout to protect the vending spout when the water-vending machine is not in use. As an alternative, water-vending machines or other water-dispensing devices may be enclosed in a room with tight-fitting walls, ceilings, and one of the following: a self-closing door, an effective air screen device, or an alternative effective device approved by the department.
- (k) Comply with the American Water Works Association (AWWA) specifications for granular activated carbon if used in the treatment of potable water (AWWA B604-74).
- (l) Be maintained in a clean and sanitary condition, free from dirt and vermin.
- (m) Use a state approved and regulated public water supply or private water source.
- (n) Be located in an area that can be maintained in a clean condition and in a manner that avoids insect and rodent harborage.
- (o) Be equipped with monitoring devices designed to shut down the labeled purified water delivery system if treatment of water by the machine does not result in a total dissolved solids content of less than 10 milligrams per liter in the purified water. Alternatively, machines shall be monitored daily at startup and manually shutdown whenever the total dissolved solids content exceeds 10 milligrams per liter in the purified water.

**111095.** It shall be unlawful to operate a bottled plant water plant, water-vending machine, retail water facility, or private water source in violation of the minimum health standards of this article.

**111100.** It is unlawful for any person to operate a water vending machine in this state which does not satisfy the minimum standards prescribed by this article for the design, construction, and sanitation of water-vending machines.

**111105.** The department, upon the request of a local health officer, may authorize the local health officer to implement and enforce those provisions of this article which relate to water-vending machines, retail water facilities, and water haulers under the terms and conditions specified by the department.

**111110.** No water-vending machine shall be used in this state which does not at least satisfy the minimum standards adopted by the department.

**111115.** The department shall require that each water-vending machine, retail water treatment plant, water hauler vehicle and facility, and private water source be maintained in a clean and sanitary condition at all times.

**111120.** (a) No person shall operate a water-bottling plant, a private water source, or be a bottled water distributor in this state except pursuant to a license issued by the department. If a person has a valid water-bottling plant license issued by the department, additional license fees for a private water source operator, a retail water facility, a water hauler, or a bottled water distributor based and operating at the same address, shall not be required.

(b) No person shall own or operate a water-vending machine or a retail water facility or be a water hauler, except pursuant to a license issued by the department or to a permit issued by a local health department.

(c) It shall be unlawful for any person to bottle, collect, treat, hold, distribute, haul, vend, or sell bottled water, vended water, operate a retail water facility, or operate a private water source without the license as required by this article. Any bottled water or vended water dispensed by a retail water facility or a private water source that is not licensed in compliance with this article is misbranded and may be embargoed pursuant to subdivision (e) of Section 111120.

(d) It shall be unlawful for a water bottler, distributor, vendor, retail water facility operator, or private water source operator to sell or otherwise distribute water that is adulterated, as defined in Section 110445, 110545, 110560, or 110565, or that is misbranded as defined in Article 6 (commencing with Section 110660) of Chapter 5.

(e) For the purposes of enforcing this section, water may be embargoed pursuant to Section 111860 in its immediate container, well, spring, spring vault, holding tank, water hauling vehicle, retail water treatment system, spigot, or pipe if there is reasonable cause to believe that it is adulterated.

(f) Any retail water facility, water vendor, or water hauler which violates this article may be subjected to the same penalty and enforcement procedure provided for violation of this article by a water bottling facility.

**111125.** No bottled water produced in an out-of-state bottling plant shall be sold or distributed within this state unless either the out-of-state bottler or the distributor shall have first obtained a bottler's or distributor's license.

**111130.** (a) The department shall charge and collect a fee for each license application submitted in accordance with the fee schedule in Table 1, which shall be an amount reasonably necessary to produce sufficient revenue to enforce the provisions of this article. The fees collected shall be adjusted annually as required by Section 100425. New applicants for a water bottling plant license shall pay Category 2 fees for the first license year.

(b) The water-bottling plant and bottled water distributor categories shall be determined by dividing by 52 the number of gallons produced or shipped into California during the previous year. If the result is an average of 5,000 gallons or less per week, the firm is Category 1. If the average exceeds 5,000 gallons per week, the firm is Category 2.

Table 1  
License Fees

<u>License Class</u>	<u>Annual Fee*</u>
Water-Bottling Plant	
Category 1	\$341.34
Category 2	963.50
Water-Vending Machine	11.26
Water Hauler	341.34
Retail Water Facility	341.34
Private Water Source Operator	341.34
Bottled Water Distributor	341.34

*\* Revised to show the "year 2000" fees*

(c) The owners or operators of each water-bottling plant, retail water facility, private water source, each water hauler in California and bottlers or distributors of water bottled out-of-state shall make application for a license on forms provided by the department. Applications and license fees shall be submitted for each calendar year.

(d) Each water-vending machine owner or operator shall make application each calendar year for a license for all machines on forms provided by the department. A decal or seal provided by the department indicating a license fee has been paid shall be affixed in a prominent place to each water-vending machine in service.

**111135.** The department may deny any license application or revoke or suspend any license issued for cause. The department shall inform the person of any denial, revocation, or suspension in writing, stating with particularity reasons for the denial, revocation, or suspension.

"Cause," as used in this section, means a violation of any provision of this chapter or any regulation adopted pursuant thereto.

**111140.** The department shall charge and collect a fee for each department evaluation required to issue a new license for a water-vending machine model or a retail water facility to determine compliance with standards established by this article. The fee shall be three hundred dollars (\$300) and shall be adjusted annually as required by Section 100425.

**111145.** (a) The department shall require each bottler, distributor, or vendor of bottled water, each owner or operator of any water-vending machine, each water hauler, each retail water facility operator, each private water source operator, and each applicant for a license, to test for all substances necessary to establish conformance to standards adopted pursuant to Section 111080 at the times and frequencies the department may reasonably establish.

(b) Each product dispensed by a water-vending machine or a retail water facility shall be sampled and analyzed for coliform bacteria at least once every six months. The analysis shall be submitted to the department indicating whether the water is pure and wholesome. Analysis of vended

water or water from retail water facilities shall be submitted to the local health officers if the local health officers are authorized by the department pursuant to subdivision (b) of Section 111105.

(c) Purified waters from retail water facilities shall be analyzed by the operator for dissolved solids by conductivity measurement not less frequently than once every seven days.

(d) Purified water from vending machines shall be analyzed by the operator for the dissolved solids by conductivity measurement each time the vending machine is serviced.

**111150.** (a) All sources of bottled water, vended water, and water dispensed by a retail water facility shall be monitored annually for the presence of volatile organic compounds of potential public health concern, as specified by the United States Environmental Protection Agency in Tables 2 and 14 contained in Volume 50 of the Federal Register on pages 46904, 46923, and 46924 on November 13, 1985, or as reasonably specified by the department as a condition of licensure.

(b) In lieu of source water monitoring required by this section, a water bottler, water vendor, or a retail water facility may document that the source monitoring required by this section is conducted by another entity approved by the department, or may comply with the treatment requirements of subdivision (c).

(c) Detection in the source water of a volatile organic compound, except trihalomethanes, for which source monitoring is required pursuant to this section shall be followed immediately by a program of periodic monitoring by the water bottler, water vendor, or retail water facility to confirm the presence or absence in the source water of the volatile organic compound. If the volatile organic compound is confirmed to be present in the source water it shall be treated using granular activated carbon treatment or an equivalent treatment operated in accordance with good manufacturing practices as provided in Section 129.80 of Title 21 of the Code of Federal Regulations until the time that the concentration of the volatile organic compound does not exceed either one part per billion, or any United States Environmental Protection Agency or United States Food and Drug Administration level for drinking water, or a maximum contaminant level established by the department for bottled water.

(d) The department may exempt any water bottler, water vendor, or retail water facility from the monitoring requirements of this section for any source based on a showing satisfactory to the department that the source (1) does not contain the volatile organic compound for which monitoring is required and (2) is not vulnerable to contamination by the volatile organic compound because for surface water sources the compounds are not applied, manufactured, stored, disposed or shipped upstream, and for groundwater sources, the compounds are not applied, manufactured, stored, disposed, or shipped in the groundwater recharge basin.

**111155.** Notwithstanding any other provisions of this article, the department may require any bottler, distributor, or vendor of bottled water, any owner or operator of a water-vending machine, any water hauler, any retail water facility operator, any private water source operator, or any applicant for a license to test and submit results to the department for any substance, including organic chemical contaminants, at any time which the department believes the substance may be present in the water source and threaten the public health.

**111160.** (a) Upon a determination by the department that a particular water source is subject to potential contamination, the department shall notify the bottler, distributor, or vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator of the specific contaminants or class of contaminants which pose a potential health risk.

(b) Within 90 days after notification by the department, the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator shall conduct an analysis of the water source and submit the results of the analysis to the department.

(c) If evidence of contamination is found, the department may, by order, require the bottler, distributor, vendor of bottled water, or the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to conduct a source and product water analysis for the contaminants of concern in accordance with conditions specified by the department. The water analysis shall be conducted and reported on an annual basis, unless the department finds that reasonable action requires either more frequent or less frequent analysis.

(d) The department may, by order, require the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to reduce or eliminate the concentration of any chemical which the department determines may have an adverse effect on public health. Until an enforceable standard has been established for a chemical which may have an adverse effect on human health, the department may require treatment techniques to reduce the concentration of the contaminants which require treatment, in the department's judgment, to prevent known or anticipated adverse effects on the health of persons. The treatment system shall be designed to meet criteria designated by the department or by an independent authority approved by the department.

(e) The department may grant variances from the requirements of subdivision (d), if the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator demonstrates either of the following:

(1) That the prescribed treatment technique is not necessary to protect the health of consumers because its water source is not subject to, nor is it likely to be subject to, significant chemical contamination.

(2) An alternative treatment technique is at least as efficient in lowering the level of contaminants to be controlled.

**111165.** All testing of bottled water, bottled water sources, water distributed by water haulers, water from retail water facility, and water from vending machines shall be done by laboratories approved by the department, laboratories certified by the United States Environmental Protection Agency, laboratories certified by the primary enforcement authority in states which have been granted primacy by the United States Environmental Protection Agency, or laboratories certified (accredited) by a third-party organization acceptable to a primacy state.

**111170.** (a) Labeling and advertising of bottled water and vended water shall conform with the provisions of this section and Chapter 4 (commencing with Section 110290) of Division 21 and Part 101 of Title 21 of the Code of Federal Regulations.

(b) Each container of bottled water sold in this state, each water-vending machine, and each container provided by retail water facilities located in this state shall be clearly labeled in an easily readable format. Retail water facilities which do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

(c) Water-vending machines, retail water facilities, and private water sources which sell water at retail shall display in a position clearly visible to customers the following information:

(1) The name and address of the operator.

(2) The fact that the water is obtained from an approved public water supply or licensed private water source.

(3) A statement describing the treatment process used.

(4) If no treatment process is utilized a statement to that effect.

(5) A telephone number that may be called for further information, service, or complaints.

(d) Bottled water may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to the Food and Drug Administration Good Manufacturing Practices contained in Section 103.35 and Parts 110 and 129 of Title 21 of the Code of Federal Regulations, Sections 12235 to 12285, inclusive, of Title 17 of the California Code of Regulations, and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155. Any vended water and any water from a retail water facility may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to Article 10 (commencing with Section 114200) of Chapter 4 of Division 22 and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155.

**111175.** (a) In addition to the requirements of Section 111170, if a bottler, distributor, water hauler, retail water facility operator, or vending machine operator provides information in the labeling or advertising stating or implying that this water is of a specific water type (for example, "spring water") or treated in a specific manner (for example, "purified"), the type or treatment shall be clearly labeled in an easily readable format. In order to be so labeled, the source or treatment shall conform to the following criteria:

(1) "Artesian well water" means water from a well tapping an aquifer in which the water level will stand above the bottom of the confining bed of the aquifer, and in which the hydraulic pressure of the water in the aquifer is greater than the force of gravity. Artesian well water shall not be altered by the addition or deletion of minerals or by blending it with water from a nonartesian well water source, except that artesian well water may be filtered and shall be treated with ozone or an equivalent disinfection process.

(2) "Fluoridated water" means water containing naturally occurring or added fluoride. The label shall specify whether fluoride is naturally occurring or is added. Any water which meets the designation of this paragraph shall contain not less than 1.0 milligrams per liter fluoridization and otherwise comply with the Food and Drug Administration quality standards set forth in Section 103.35(d) (2) of Title 21 of the Code of Federal Regulations.

(3) "Mineral water" means bottled water or vended water containing more than 500 milligrams per liter of total dissolved solids and originating entirely from an underground source, which may be a well, artesian well, or spring. Bottled or vended mineral water may be derived from a natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from a natural orifice or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Mineral water may not be altered by the addition or deletion of minerals or by blending it with water from a nonmineral water source, except that mineral water may be filtered and shall be treated with ozone or an equivalent disinfection process approved by the department and shall be treated to reduce the concentrations of any naturally occurring substance which exceeds the bottled water safety standards established by the department. Mineral water may be collected and transported by pipes, tunnels, trucks, or similar devices. Any water which meets the criteria of this paragraph may also be labeled "natural mineral water."

(A) Mineral water which contains carbon dioxide as it emerges from the source and is bottled directly with its entrapped gas, or from which the gas is mechanically separated and later reintroduced into the water at the time of bottling shall be labeled "naturally carbonated" or "naturally sparkling."

(B) Mineral water which contains carbon dioxide, other than that naturally occurring in the source product, shall be labeled with the words "carbonation added" or "carbon dioxide added" when the carbonation is obtained from a natural or manufactured source.

(4) "Mineralized water" means bottled or vended water which meets the requirements of "mineral water" except that the water contains added minerals.

(5) "Natural water" means bottled or vended spring, artesian well, or well water which is unmodified by mineral addition or deletion, except "natural water" may be filtered and shall be sanitized with ozone or an equivalent disinfection process and treated to reduce the concentration of any substance which exceeds safety standards established by the department.

(6) "Naturally sparkling water" means bottled water or vended water with a carbon dioxide content from the same source as the water. "Sparkling," "carbonated," or "carbonation added" means bottled water or vended water which contains carbon dioxide.

(7) "Purified water" means water produced by distillation, deionization, reverse osmosis, or other method meeting the definition of purified water in the 21st edition of the United States Pharmacopeia. Water which meets the designation of this paragraph, and is vaporized, then condensed, may be labeled "distilled water."

~~(8) "Spring water" means water which issues by natural forces out of the earth at a particular place. Bottled or vended spring water may be derived from the natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from the natural orifice by external force or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Spring water may not be altered by the addition or deletion of minerals or by blending it with water from a nonspring water source, except that spring water may be filtered and shall be treated with ozone or an equivalent disinfection process. Spring water may be collected and transported by pipes, tunnels, trucks, or similar devices.~~

*[NOTE: The federal court in Sacramento ruled on September 22, 1997 (Case # CIV.No.S-97-1048 EJD/DAD) that the state standard of identity for "spring water" was preempted by the federal standards.]*

Federal Standard of identity for "spring water" [21CFR Section 165.110(a)(2)(vi)]:

The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be "spring water." Spring water shall be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

(9) "Well water" means water from a hole bored into the ground which taps the water of an aquifer, except that well water may be filtered and shall be treated with ozone or an equivalent disinfection process. Well water may not be altered by the addition or deletion of minerals or by blending it with water from a nonwell water source.

(10) Notwithstanding any other provision of this section, water from a public water system which is unprocessed by the bottler or vendor shall be labeled as "unprocessed public drinking water."

**111180.** Except as provided in Section 111080, any bottled water or vended water, the quality of which is below the quality required by this article, shall be labeled with a statement of substandard quality, as prescribed by Section 103.35 of Title 21 of the Code of Federal Regulations.

**111185.** Any bottler, distributor, vendor of bottled water, or owner or operator of any water-vending machine or retail water facility, whose corporate name or trademark contains the words "spring" or "springs," or any derivative of either of these words, or "well," "artesian well," or "natural" shall label each bottle or vending machine with the source of the water in typeface at least equal to the size of the typeface of the corporate name or trademark, if the source of the bottled or vended water is different from the source stated in the corporate name or trademark. Retail water facilities which do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

**111190.** (a) A bottled water, as defined in Section 111170, with natural or added carbonation, may be prepared with added flavors, extracts, essences, or fruit juice concentrates derived from a spice or fruit and comprising less than 1 percent by weight of the final product.

The final product shall contain no sweeteners, or additives other than the flavors, extracts, essences, or fruit juice concentrates and carbon dioxide and shall be designated on labels and in advertising as follows:

(1) The common or usual name of the characterizing flavor shall accompany the designation of the bottled water product type as defined in subdivision (b) of Section 111170.

(2) The product may be designated as "natural" only if it meets the requirements for the designation as defined in paragraphs (5) and (6) of subdivision (b) of Section 111170, and naturally derived flavors, extracts, or essences are used.

(b) Products labeled pursuant to this section shall comply with all other provisions of this article. Products with one type or one source of bottled water that are labeled pursuant to this section shall not be blended with water that is not bottled water or that is of another bottled water type.

**111195.** The department, prior to issuing a license, shall review all labels prepared pursuant to this article, and may require any changes in order to comply with the provisions of this article.

**SANITATION REQUIREMENTS FOR VENDING MACHINES  
CALIFORNIA HEALTH AND SAFETY CODE  
CALIFORNIA UNIFORM RETAIL FOOD FACILITIES LAW  
SECTIONS 114200 - 114245**

**114200.** This article governs sanitation requirements for vending machines as defined in this chapter.

**114205 .** Each vending machine or machine location shall have posted in a prominent place a sign indicating the owner's name, address, and telephone number.

**114210.** All food shall be stored and packaged in clean, protected containers, and handled, transported, and vended in a sanitary manner. Wet storage of packaged products is prohibited.

Potentially hazardous food shall be dispensed to the consumer in the original package into which it was placed at the commissary or processing plant. Bulk potentially hazardous food is prohibited.

**114215.** All food contact surfaces shall be cleaned and sanitized either in place in a machine so designed and approved or by removing from the machine and cleaning and sanitizing at an approved facility.

All food contact surfaces when removed from the machine after cleaning and sanitizing shall be protected from contamination before being returned to the machine.

A record of cleaning and sanitizing shall be maintained by the operator in each machine and shall be current for at least the past 30 days.

**114220.** Single-service containers which are used in machines dispensing products in bulk, shall be obtained in sanitary packages, shall be stored in a clean, dry place until used, and shall be handled in a sanitary manner. The containers shall be stored in the original package until introduced into the container magazine or dispenser of the vending

machine. The containers stored within the vending machine shall be protected from manual contact, dirt, vermin, and other contamination.

**114225.** Each vending machine shall be located in a room, area, or space which shall minimize the potential for contamination of food. The floor area upon which vending machines are located shall be smooth, of cleanable construction, and capable of withstanding repeated washing and scrubbing.

**114230.** Water used in vending machines shall be potable.

**114235.** While in transit to machine locations, food, single-service containers, and equipment shall be protected from dirt, vermin, and other contamination.

**114240.** On or after January 1, 1985, all vending machines shall be constructed in accordance with National Sanitation Foundation or National Automatic Merchandizing Association standards, or the equivalent thereof.

**114245.** Vending machines shall meet all the requirements of Article 6 (commencing with Section 113975) and applicable sections of Article 7 (commencing with Section 113990).

**FOOD SANITATION - FOOD PROCESSING ESTABLISHMENTS**  
**CALIFORNIA HEALTH AND SAFETY CODE**  
**SECTIONS 111950 - 112055**

**111950.** "Food," as used in this chapter, includes all articles used for food, drink, confectionery, or condiment. Whether simple or compound, and all substances and ingredients used in the preparation thereof.

**111955.** "Food processing establishment," as used in this chapter, shall mean any room, building or place or portion thereof, maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, canning, packing, slaughtering or otherwise preparing or handling food except restaurants.

**111960.** Every food processing establishment shall be properly lighted, drained, plumbed, and ventilated; and shall be conducted with strict regard to the influence of lighting, drainage, plumbing, and ventilation upon the health of persons therein employed, and upon the purity and wholesomeness of the food therein produced, prepared for sale, manufactured, packed, stored, kept, handled, sold, or distributed.

**111965.** The floors, side walls, ceiling, furniture, receptacles, utensils, implements, and machinery of every food processing establishment shall at no time be kept in an unclean, unhealthful, or unsanitary condition.

Any of the following is deemed to be "an unclean, unhealthful, or unsanitary condition":

(a) If food in the process of manufacture, preparation, packing, storing, sale, or distribution is not securely protected from flies, dust, or dirt, and from all other foreign or injurious contamination.

(b) If refuse, dirt, and waste products subject to decomposition and fermentation incident to the manufacture, preparation, packing, storing, selling, and distributing of food, are not removed daily.

(c) If all trucks, trays, boxes, baskets, buckets, other receptacles, chutes, platforms, racks, tables, shelves, knives, saws, cleavers, and all other utensils, receptacles, and machinery used in moving, handling, cutting, chopping, mixing, canning, and all other processes employed in the preparation of food are not thoroughly cleaned daily.

(d) If the clothing of employees is unclean or if they dress, undress, or leave or store their clothing in the place where the food is produced, prepared, manufactured, packed, sold or distributed.

**111970.** No live animal or fowl shall be kept or allowed in any establishment where food is prepared, manufactured, kept, stored, offered for sale or sold unless such establishment is exclusively devoted to the slaughter, processing and/or sale of such animal or fowl. This section does not apply to dogs used by uniformed employees of private patrol operators and operators of a private patrol service who are licensed pursuant to Chapter 11 (commencing with Section 7500) of Division 3 of the Business and Professions Code, while such employees are acting within the course and scope of their employment as private patrolmen.

The state department may adopt rules and regulations as it determines are reasonably necessary under this section for the protection of the public health and safety.

**111975.** The side walls and ceilings of every bakery, confectionery, hotel, or restaurant kitchen shall be well plastered with metal or lumber, or shall be oil painted or kept well lime washed, or otherwise kept in a good sanitary condition.

**111980.** All interior woodwork of every bakery, confectionery, hotel, or restaurant kitchen shall be kept well oiled or painted with oil paint, and shall be kept washed clean with soap and water, or otherwise kept in a good sanitary condition.

**111985.** Every building, room, basement, or cellar occupied or used for the preparation, manufacture, packing, storage, sale or distribution of food shall have an impermeable floor, made of cement, or of tile laid in cement, brick, wood, or other suitable, nonabsorbent material which can be flushed and washed clean with water.

**111990.** Where practicable, the doors, windows, and other openings of every food producing or distributing establishment shall be fitted with stationary or self-closing screen doors and wire window screens, of not coarser than 14 mesh wire gauze.

**111995.** Every building, room, basement, or cellar occupied or used for the production, preparation, manufacture, packing, canning, sale, or distribution of food shall have convenient toilet or toilet-rooms, separate and apart from the room or rooms where the process of production, preparation, manufacture, packing, canning, selling, or distributing is conducted.

**112000.** The floors of toilet-rooms shall be made of cement, or of tile laid in cement, wood, brick, or other nonabsorbent material, and shall be washed and scoured daily.

**112005.** The toilets shall be furnished with separate ventilating pipes or flues discharging either into soil pipes or on the outside of the building in which they are situated.

**112010.** Lavatories and washrooms shall be adjacent to toilet-rooms and shall be supplied with soap, running water, and towels, and shall be maintained in a clean and sanitary condition.

**112015.** Employees and others who handle the material from which food is prepared or the finished product shall before beginning work and immediately after visiting a toilet or lavatory, wash their hands and arms thoroughly in clean water.

**112020.** No employee or other person shall sit or lie upon any table, bench, trough, shelf, or other equipment which is intended for use in connection with any food manufacturing process.

**112025.** No employee or other person shall expectorate or discharge any substance from his nose or mouth on the floor or interior side wall of any building, room, basement, or cellar where the production, preparation, manufacture, packing, storing, or sale of any food is conducted.

**112030.** No person shall, nor shall any person be allowed to, reside or sleep in any room of a bake-shop, public dining-room, hotel or restaurant kitchen, confectionery, or other place where food is prepared, produced, manufactured, served, or sold.

**112035.** No employer shall require or permit any person to work, in a food processing establishment or vehicle used for the production, preparation, manufacture, sale, or transportation of food if the person is infected with any contagious, infectious, or communicable disease which can be transmitted by the food involved.

**112040.** The state department, its inspectors and agents, and all local health officers and inspectors may at all times enter any building, room, basement, cellar, or other place occupied or used, or suspected of being occupied or used, for the production, preparation, manufacture, storage, sale or distribution of food, and inspect the premises and all utensils, implements, receptacles, fixtures, furniture, and machinery used.

**112045.** If upon inspection any such building, room, basement, cellar, or other place, or any vehicle, employer, employee, or other person is found to be in violation of or violating any of the provisions of this article, or if the production, preparation, manufacture, packing, storing, sale, or distribution of food is being conducted in a manner detrimental to the health of the employees or to be character or quality of the food being produced, prepared,

manufactured, packed, stored, sold, distributed, or conveyed, the person making the inspection shall at once make a written report of the violation to the district attorney of the county, who shall prosecute the violator. He shall make a like report to the state department. The state department, from time to time, may publish such reports in its monthly bulletin.

**112050.** Every building, room, basement, cellar, or other place or thing kept, maintained, or operated in violation of this article, and all food produced, prepared, manufactured, packed, stored, kept, sold, distributed, or transported in violation of this article, is a public nuisance dangerous to health. Any such nuisance may be abated or enjoined in an action brought for that purpose by the local or state department or may be summarily abated in the manner provided by law for the summary abatement of public nuisances dangerous to health.

**112055.** The sections contained in this article are to be known as the California Food Sanitation Act.

**SANITATION IN FOOD PLANTS**  
**CALIFORNIA ADMINISTRATIVE CODE, TITLE 17**  
**CHAPTER 5, SUBCHAPTER 2, GROUP 1**  
**ARTICLE 7, SECTIONS 12245 - 12280**

**12245. General Plant Sanitation; Floors, Walls, Ceilings, Etc.**

The floors, walls, ceilings, partitions, posts, doors and other parts of all preparation and processing areas shall be of such materials, construction and finish that they may be readily and thoroughly cleaned. The floors in all areas where water is used in the operation are to be so constructed and of such material as to be watertight and they shall be maintained in such condition as to stay watertight. All areas used for edible products shall be separate and distinct from those used for inedible products, such as fish meal reduction plants.

**12250. Areas, Equipment, and Operations to Be Sanitary.**

(a) Areas, equipment and utensils used for preparing, storing, or otherwise handling any food product and all other parts of the establishment shall be kept clean and in a sanitary condition. Areas in which any food product is prepared, processed, stored or handled, including walls, ceilings, and overhead structures of such areas, shall be kept as reasonably free from moisture as is practicable. In such areas there shall be no dripping from any source, including ceilings and overhead structures, that may contaminate the product.

(b) Equipment and utensils used for preparing, processing or otherwise handling any food product shall be of such materials and construction that they can be readily and thoroughly cleaned. Pipelines used to convey fluid or semi-fluid products shall be so constructed that they can be readily and thoroughly cleaned.

(c) Operations and procedures involving the preparation, storing or handling of any food product shall be strictly in accord with good sanitary practice.

**12255. Use of Poisonous Insecticides and Rodenticides.**

(a) Every practical precaution shall be taken to keep establishments free from flies, rats, mice and other vermin. If necessary, rodent-proof rooms shall be provided for materials which might become contaminated by these pests.

(b) The use of insecticides, or rodenticides, toxic to humans, in areas where any food products, not adequately protected, is being stored or handled is prohibited.

(c) Poisonous insecticides and rodenticides may be used under buildings, wharves, outbuildings, or similar places, or where adequately protected packaged products are stored; only, if adequate precautions are taken to eliminate the possibility of said poisons being accidentally spilled, or carried, by any means, to areas where these poisons are prohibited. These poisons are to be adequately protected from possible contact by children, or domestic animals, and are to be plainly and distinctly labeled for identification by adults.

**12260. Empty Container Storage.**

Empty cans, jars, lids, covers, barrels, drums, etc., must be clean when filled with food products.

**12275. Personal Hygiene.**

(a) The employees of the establishment who handle any food product shall keep their hands clean; and, after visiting the toilet room or urinals, shall wash their hands before handling any food product or implement used in the preparation of the product.

(b) Outer clothing and gloves worn by persons who handle any food product shall be clean and of material that can be readily cleaned.

(c) Such practices as spitting on the floor and using empty cans, jars, or other containers as drinking cups, or for purposes other than those originally intended, are forbidden.

(d) Care shall be taken to prevent the contamination of food products with perspiration, hair, cosmetics, medicaments and the like. Adequate head coverings must be worn by all men and women while engaged in the preparation or handling of any food product.

(e) Smoking by any person shall not be permitted while preparing or handling any food product or while handling empty cans, jars, lids, barrels, drums or other receptacles used for food products.

(f) The use of fingernail polish by any person preparing, processing, or handling any food product without gloves whereby the product might become contaminated, is prohibited.

(g) No clothing, shoes, boots, aprons, etc. shall be kept or stored in any area where any food product is prepared, processed, or handled; except, in or on facilities specifically provided for this purpose.

**12280. Sanitary Facilities.**

Adequate sanitary facilities and accommodations shall be furnished by every food packing establishment. Of these the following are specifically required:

(a) Dressing rooms, and toilet and urinal rooms shall be sufficient in number and conveniently located. These rooms shall be well lighted, sufficiently ventilated to insure sanitary conditions, vented to the outside, and meet all requirements as to sanitary construction and equipment. All doors entering such rooms shall be self-closing. All windows shall be screened. Such rooms shall be separate from areas in which food products are prepared, stored, or handled. The walls, ceiling, partitions, and other parts of all dressing rooms, toilet rooms, lavatory rooms and urinal rooms shall be of light color and of such construction as to be easily and adequately cleaned. Where five or more persons of both sexes are employed, separate facilities shall be provided for each sex.

(b) Sanitary washing facilities, including running hot and cold water, soap and individual towels, shall be provided, and shall be placed in or near toilet and urinal rooms and also at other places in the establishment as may be essential to insure cleanliness of all persons handling any food product.

(c) Adequate lockers or cloak rooms for all employees shall be provided and shall be kept clean and well ventilated.

(d) Toilet soil lines shall be kept separate from industrial waste lines to a point outside the buildings. Drainage from toilet bowls and urinals shall not be discharged into grease salvage basins, or into open disposal systems.

**BOTTLED WATER QUALITY STANDARDS**  
**TITLE 21, CODE OF FEDERAL REGULATIONS**  
**SECTIONS 165.3 and 165.110(b)**

**§165.3 Definitions.**

(a) A lot is:

(a)(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(a)(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A sample consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An analytical unit is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

**Subpart B--Standards of Quality**

**165.110(b) Quality.**

(b) Quality. The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water"), is as follows:

(b)(1) Definitions. (i) Trihalomethane (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(b)(1)(ii) Total trihalomethane (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane and tribromomethane), rounded to two significant figures.

(b)(2) Microbiological quality. Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 1015 15th St., NW., Washington, DC 20005, or a copy may be examined at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition's Library, 200 C St., SW., Washington, DC), meet the following standards of microbiological quality:

(b)(2)(i) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(b)(2)(ii) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(b)(3) Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:

(b)(3)(i) The turbidity shall not exceed 5 units.

(b)(3)(ii) The color shall not exceed 15 units<sup>1</sup>.

1Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(b)(3)(iii) The odor shall not exceed threshold odor No. 3<sup>1</sup>.

(b)(4) Chemical quality. (i)(A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in milligrams per liter
Arsenic	0.05
Chloride <sup>1</sup>	250.0
Iron <sup>1</sup>	0.3
Manganese <sup>1</sup>	0.05
Phenols	0.001
Total dissolved solids <sup>1</sup>	500.0
Zinc <sup>1</sup>	5.0

Organics:

Endrin (1,2,3,4,10,10-hexachol- ro-6, 7-epoxy 1,4,4a,5,6,7,8, 8a-octahydro-1,4-endo, endo-5,8-dimethan enaphthalene)  
0.0002

Total Trihalomethanes 0.10

<sup>1</sup>Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(b)(4)(i)(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), or "Methods for Chemical Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(b)(4)(i)(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i) (C)(1) and (C)(2) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in "Standard Methods for Examination of Water and Wastewater," 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 1015 Fifteenth St., NW., Washington DC 20005, and examined at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington DC, or the Center for Food Safety and Applied Nutrition's Library, 200 C St. NW., Washington DC. The methods in paragraphs (b)(4)(i)(C)(3) and (C)(4) are cross-referenced in 40 CFR part 141, subpart C, appendix C.

(1) "Methods for Organochlorine Pesticides in Industrial Effluents;"

(2) "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973;

(3) "Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;" which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(4) "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(b)(4)(ii)(A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8-58.3	2.2
58.4-63.8	2.0
63.9-70.6	1.8
70.7-79.2	1.6
79.3-90.5	1.4

(b)(4)(ii)(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(b)(4)(ii)(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8-58.3	1.5
58.4-63.8	1.3
63.9-70.6	1.2
70.7-79.2	1.0
79.3-90.5	0.8

(b)(4)(ii)(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(b)(4)(iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(b)(4)(iii)(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter <- (or as specified)
Antimony	.006. 10-01-98
Barium	2.
Beryllium	0.004. 10-01-98
Cadmium	0.005.
Chromium	0.1.
Copper	1.0.
Cyanide	0.2. 10-01-98
Lead	0.005.
Mercury	0.002.
Nickel	0.1 10-01-98
Nitrate	10 (as nitrogen).
Nitrite	1 (as nitrogen).
Total Nitrate and Nitrite	10 (as nitrogen).
Selenium	0.05.

Thallium

0.002. 10-01-98

(b)(4)(iii)(B) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant £ (CAS Reg. No.)      Concentration in milligrams per liter

Benzene (71-43-2)	0.005
Carbon tetrachloride (56-23-5)	0.005
o- Dichlorobenzene (95-50-1)	0.6
p- Dichlorobenzene (106-46-7)	0.075
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
cis-1,2-Dichloroethylene (156-59-2)	0.07
trans-1,2-Dichloroethylene (156-60-5)	0.1
Dichloromethane (75-09-2)	0.005
1,2-Dichloropropane (78-87-5)	0.005
Ethylbenzene (100-41-4)	0.7
Monochlorobenzene (108-90-7)	0.1
Styrene (100-42-5)	0.1
Tetrachloroethylene (127-18-4)	0.005
Toluene (108-88-3)	1
1,2,4-Trichlorobenzene (120-82-1)	0.07
1,1,1-Trichloroethane (71-55-6)	0.20
1,1,2-Trichloroethane (79-00-5)	0.005
Trichloroethylene (79-01-6)	0.005
Vinyl chloride (75-01-4)	0.002
Xylenes (1330-20-7)	10

(b)(4)(iii)(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant £ (CAS Reg. No.)      Concentration in milligrams per liter

Alachlor (15972-60-8)	0.002
Atrazine (1912-24-9)	0.003
Benzo(a)pyrene (50-32-8)	0.0002
Carbofuran (1563-66-2)	0.04
Chlordane (57-74-9)	0.002
Dalapon (75-99-0)	0.2
1,2-Dibromo-3-chloropropane (96-12-8)	0.0002
2,4-D (94-75-7)	0.07
Di(2-ethylhexyl)adipate (103-23-1)	0.4
Dinoseb (88-85-7)	0.007
Diquat (85-00-7)	0.02 10-01-98
Endothall (145-73-3)	0.1 10-01-98
Endrin (72-20-8)	0.002
Ethylene dibromide (106-93-4)	0.00005
Glyphosate (1071-53-6)	0.7 10-01-98
Heptachlor (76-44-8)	0.0004
Heptachlor epoxide (1024-57-3)	0.0002
Hexachlorobenzene (118-74-4)	0.001

Hexachlorocyclopentadiene (77-47-4)	0.05
Lindane (58-89-9)	0.0002
Methoxychlor (72-43-5)	0.04
Oxamyl (23135-22-0)	0.2
Pentachlorophenol (87-86-5)	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)	0.0005
Picloram (1918-02-1)	0.5
Simazine (122-34-9)	0.004
2,3,7,8-TCDD (Dioxin) (1746-01-6)	$3 \times 10^{-8}$ 10-01-98
Toxaphene (8001-35-2)	0.003
2,4,5-TP (Silvex) (93-72-1)	0.05

(b)(4)(iii)(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1
Sulfate <sup>1</sup>	250.0

<sup>1</sup>Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(b)(4)(iii)(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(1) through (b)(4)(iii)(E)(13) of this section and described, unless otherwise noted, in "Methods for Chemical Analysis of Water and Wastes," U.S. EPA Environmental Monitoring and Support Laboratory (EMSL), Cincinnati, OH 45258 (EPA-600/4-79-020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(1) Antimony shall be measured using the following methods:

(1)(i) Method 204.2-"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(1)(ii) Method 200.8-"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(1)(iii) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(1)(iv) Method D-3697-92—"Standard Test Method for Antimony in Water," contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(2) Barium shall be measured using the following methods:

(2)(i) Method 208.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(2)(ii) Method 208.1—"Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(2)(iii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3) Beryllium shall be measured using the following methods:

(3)(i) Method 210.2—"Atomic Absorption; Furnace Technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(3)(ii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3)(iii) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3)(iv) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(4) Cadmium shall be measured using the following methods:

(4)(i) Method 213.2—"Atomic Absorption; Furnace Technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(4)(ii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(5) Chromium shall be measured using the following methods:

(5)(i) Method 218.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(5)(ii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(6) Copper shall be measured as total recoverable metal without filtration using the following methods:

(6)(i) Method 220.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(6)(ii) Method 220.1—"Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(6)(iii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(6)(iv) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(II) OF THIS SECTION.

(6)(v) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(7) Cyanide shall be measured using the following methods:

(7)(i) Method 335.1—"Titrimetric; Spectrophotometric" which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(7)(ii) Method 335.2—"Titrimetric; Spectrophotometric" which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(7)(iii) Method 335.3—"Colorimetric, Automated UV," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(7)(iv) Method D-2036-91—"Standard Test Methods for Cyanides in Water," contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(8) Lead shall be measured as total recoverable metal without filtration using the following methods:

(8)(i) Method 239.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(8)(ii) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(8)(iii) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(9) Mercury shall be measured using the following methods:

(9)(i) Method 245.1—"Manual cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(9)(ii) Method 245.2—"Automated cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(10) Nickel shall be measured using the following methods:

(10)(i) Method 249.1—"Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(10)(ii) Method 249.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(10)(iii) Method 200.7—"Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(10)(iv) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(10)(v) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(b)(11) Nitrate and/or nitrite shall be measured using the following methods:

(11)(i) Method 300.0—"The Determination of Inorganic Anions in Water by Ion Chromatography-Method 300.0," EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from NTIS, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C Street SW., Washington, DC 20204, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(11)(ii) Method 353.1—"Colorimetric, automated, hydrazine reduction," for nitrate only, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(11)(iii) Method 353.2—"Colorimetric, automated, cadmium reduction," for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(11)(iv) Method 353.3—"Spectrophotometric, cadmium reduction," for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(12) Selenium shall be measured using the following methods:

(12)(i) Method 270.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(12)(ii) Method 270.3—"Atomic Absorption; gaseous hydride," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(13) Thallium shall be measured using the following methods:

(13)(i) Method 279.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(13)(ii) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(13)(iii) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(b)(4)(iii)(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(20) of this section and described, unless otherwise noted, in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, EMSL, EPA/600/4-88/039, December 1988, or in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1," Office of Research and Development, EMSL, EPA/600/4-90/020, July 1990, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) Method 502.1—"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(2) Method 502.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(3) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(4) Method 524.1—"Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (5) Method 524.2—"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (6) Method 504—"1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (7) Method 505—"Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, hexachlorocyclopentadiene, simazine, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (8) Method 506—"Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection," applicable to di(2-ethylhexyl) adipate which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (9) Method 507—"Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector," Rev. 2.0, 1989, (applicable to alachlor, atrazine, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (10) Method 508—"Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector," Rev. 3.0, 1989, (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (11) Method 508A—"Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography," Rev. 1.0, 1989, (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508 in paragraph (b)(4)(iii)(F)(7) or (b)(4)(iii)(F)(9) of this section, respectively, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (12) Method 515.1—"Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector," Rev. 5.0, 1991, (applicable to 2,4-D, 2,4,5-TP (Silvex), pentachlorophenol, dalapon, dinoseb, and picloram), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (13) Method 525.1—"Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 2.2, May 1991, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, pentachlorophenol, benzo(a)pyrene, di(2-ethylhexyl) adipate, endrin, hexachlorobenzene, hexachlorocyclopentadiene, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (14) Method 531.1—"Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization," Rev. 3.0, 1989, (applicable to carbofuran and oxamyl (vydate)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (15) Method 547—"Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection HPLC, Post-Column Derivatization, and Fluorescence Detection," (applicable to glyphosate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (16) Method 548—"Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron-Capture Detection," (applicable to endothall), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (17) Method 549—"Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid Extraction and HPLC with Ultraviolet Detection," (applicable to diquat), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (18) Method 550—"Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (19) Method 550.1—"Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a)pyrene and other polynuclear

aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.

(20) Method 1613—"Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS," Rev. A, 1990, EPA, Office of Water Regulations and Standards, Industrial Technology Division, (applicable to 2,3,7,8-TCDD (Dioxin)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from USEPA-OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b)(4)(iii)(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(1) through (b)(4)(iii)(G)(3) of this section and described, unless otherwise noted, in "Methods of Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(1) Aluminum shall be measured using the following methods:

(1)(i) Method 202.1—"Atomic Absorption; direct aspiration technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(1)(ii) Method 202.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E).

(1)(iii) Method 200.7—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(1)(iv) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(1)(v) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(2) Silver shall be measured using the following methods:

(2)(i) Method 272.1—"Atomic Absorption; direct aspiration technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(2)(ii) Method 272.2—"Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(2)(iii) Method 200.7—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(2)(iv) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460,

(EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(2)(v) Method 200.9—"Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(3) Sulfate shall be measured using the following methods:

(3)(i) Method 300.0—"The Determination of Inorganic Anions in Water by Ion Chromatography-Method 300.0," EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(i) of this section.

(3)(ii) Method 375.1—"Colorimetric, Automated, Chloranilate," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(3)(iii) Method 375.3—"Gravimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(3)(iv) Method 375.4—"Turbidimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.10-01-98

(b)(5) Radiological quality. (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(b)(5)(i)(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(b)(5)(i)(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(b)(5)(i)(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(b)(5)(ii) Analyses conducted to determine compliance with paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), and "Interim Radiochemical Methodology for Drinking Water," U.S. EPA, EMSL, EPA-600/4-75-008 (Revised), March 1976, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (b)(2) of this section.

(c) Label statements. When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in §130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in §130.14(a) the following statement(s) shall be used:

(c)(1) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of paragraph (b)(2) of this section.

(c)(2) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.

(c)(3) "Contains Excessive \_\_\_\_," with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes") except that "Contains Excessive Chemical Substances" may be used if the bottled water is not mineral water.

(c)(4) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) Adulteration. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section.

[Reference: 60 FR 57076 to 57130, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769 May 11, 1998]

*[Note: The text version of the 21 CFR Sections was downloaded from the "Keller-Soft Food Quality & Safety Software". Please see the reference shown above for further information.]*

**PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER**  
**TITLE 21, CODE OF FEDERAL REGULATIONS**  
**PART 129**

**Subpart A--General Provisions**

**129.1 Current good manufacturing practice.**

The applicable criteria in Part 110 of this chapter, as well as the criteria in subsections 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

**129.3 Definitions.**

For the purposes of this part, the following definitions apply:

(a) "Approved source" when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.

(b) "Bottled drinking water" means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) "Lot" means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(d) "Multiservice containers" means containers intended for use more than one time.

(e) "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

(f) "Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) "Primary container" means the immediate container in which the product water is packaged.

(h) "Product water" means processed water used by a plant for bottled drinking water.

(i) "Shall and should." "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) "Shipping case" means a container in which one or more primary containers of the product are held.

(k) "Single-service container" means a container intended for one time usage only.

(l) "Unit package" means a standard commercial package of bottled drinking water, which may consist of one or more containers.

## **Subpart B--Buildings and Facilities**

### **129.20 Plant construction and design.**

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

### **129.35 Sanitary facilities.**

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) Product water and operations water--(1) Product water. The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) Operations water. If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) Product water and operations water from approved sources. (i) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once

each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. This sampling is in addition to any performed by government agencies having jurisdiction. Records of approval of the source water by government agencies having jurisdiction and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in Section 103.35 of this chapter.

(iii) Analysis of the samples may be performed for the plant by competent commercial laboratories.

(b) Air under pressure. Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

(c) Locker and lunchrooms. When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

### **129.37 Sanitary operation.**

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

## **Subpart C--Equipment**

### **129.40 Equipment and procedures.**

(a) Suitability. (1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) Design. Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

## **Subpart E--Production and Process Controls**

### **129.80 Processes and controls.**

(a) Treatment of product water. All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) Containers. (1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) Cleaning and sanitizing solutions. Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) Sanitizing operations. Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was

in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170° F for at least 15 minutes or at least 200° F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170° F for at least 15 minutes or at least 200° F for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57° F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57° F or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) When containers are sanitized using a substance other than one provided for in Section 178.1010 of this chapter, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.

(e) Unit package production code. Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

(f) Filling, capping, or sealing. During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

(g) Compliance procedures. A quality standard for bottled drinking water, excluding mineral water, is established in Section 103.35 of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.

(2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) Record retention. All records required by sections 129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

## U. S. PHARMACOPEIA PURIFIED WATER

Purified Water is water obtained by distillation, ion-exchange treatment, reverse osmosis, or other suitable process. It is prepared from water complying with the regulations of the federal Environmental Protection Agency with respect to drinking water. It contains no added substance.

NOTE--Purified Water is intended for use as an ingredient in the preparation of compendial dosage forms. Where used for sterile dosage forms, other than for parenteral administration, process the article to meet the requirements under Sterility Tests 71, or first render the Purified Water sterile and thereafter protect it from microbial contamination. Do not use Purified Water in preparations intended for parenteral administration. For such purposes use Water for Injection, Bacteriostatic Water for Injection, or Sterile Water for Injection.

**Packaging and storage**--Where packaged, preserve in tight containers.

**Labeling**--Where packaged, label it to indicate the method of preparation.

**pH** 791 : between 5.0 and 7.0, determined potentiometrically in a solution prepared by the addition of 0.30 mL of saturated potassium chloride solution to 100 mL of test specimen.

**Chloride**--To 100 mL add 5 drops of nitric acid and 1 mL of silver nitrate TS: no opalescence is produced.

**Sulfate**--To 100 mL add 1 mL of barium chloride TS: no turbidity is produced.

**Ammonia**--To 100 mL add 2 mL of alkaline mercuric-potassium iodide TS: any yellow color produced immediately is not darker than that of a control containing 30ug of added  $\text{NH}_3$  in High-purity Water (see under Reagents in Containers 661) [0.3 ppm].

**Calcium**--To 100 mL add 2 mL of ammonium oxalate TS: no turbidity is produced.

**Carbon dioxide**--To 25 mL add 25 mL of calcium hydroxide TS: the mixture remains clear.

**Heavy metals**--Adjust 40 mL of Purified Water with 1 N acetic acid to a pH of 3.0 to 4.0 (using short-range pH indicator paper), add 10 mL of freshly prepared hydrogen sulfide TS, and allow the liquid to stand for 10 minutes: the color of the liquid, when viewed downward over a white surface, is not darker than the color of a mixture of 50 mL of the same Purified Water with the same amount of 1 N acetic acid as was added to the test specimen, matched color-comparison tubes being used for the comparison.

**Oxidizable substances**--To 100 mL add 10 mL of 2 N sulfuric acid, and heat to boiling. Add 0.1 mL of 0.1 N potassium permanganate, and boil for 10 minutes; the pink color does not completely disappear.

**Total solids**--Evaporate 100 mL on a steam bath to dryness, and dry the residue at 105° for 1 hour: not more than 1 mg of residue remains (0.001%).

**Bacteriological purity**--It complies with the federal Environmental Protection Agency regulations for drinking water with respect to bacteriological purity (40 CFR 141.14; 141.21).

**CURRENT GOOD MANUFACTURING PRACTICE  
IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD  
TITLE 21, CODE OF FEDERAL REGULATIONS  
PART 110**

**Subpart A--General Provisions**

**110.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.
- (b) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) "Batter" means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) "Blanching," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) "Critical control point" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) "Food" means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) "Food-contact surfaces" are those surfaces that contact human food and those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- (h) "Lot" means the food produced during a period of time indicated by a specific code.
- (i) "Microorganisms" means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.
- (j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- (n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity ( $a_w$ ). An  $a_w$  will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.
- (o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- (p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "Water activity" ( $a_w$ ) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

### **110.5 Current good manufacturing practice.**

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

### **110.10 Personnel.**

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

#### **110.19 Exclusions.**

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

### **Subpart B--Buildings and Facilities**

#### **110.20 Plant and grounds.**

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborage for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

### **110.35 Sanitary operations.**

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and
- (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

#### **110.37 Sanitary facilities and controls.**

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.  
(2) Properly convey sewage and liquid disposable waste from the plant.  
(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.  
(2) Keeping the facilities in good repair at all times.  
(3) Providing self-closing doors.  
(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.  
(3) Sanitary towel service or suitable drying devices.  
(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and official disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

### **Subpart C--Equipment**

#### **110.40 Equipment and utensils.**

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

### **Subpart E--Production and Process Controls**

#### **110.80 Processes and controls.**

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of micro-organisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a<sub>w</sub>, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

- (i) Maintaining refrigerated foods at 45° F (7.2° C) or below as appropriate for the particular food involved.
- (ii) Maintaining frozen foods in a frozen state.
- (iii) Maintaining hot foods at 140° F (60° C) or above.
- (iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined that found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in { 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of  $a_w$  for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the  $a_w$  of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the  $a_w$  of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

### **110.93 Warehousing and distribution.**

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

## **Subpart G--Defect Action Levels**

### **110.110 Natural or unavoidable defects in food for human use that present no health hazard.**

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. S.W., Washington, DC 20204.